ProVee®

Physician Information

The information provided below is intended solely for use by healthcare professionals and physicians. It is not intended for patients or the general public.

MRI Safety Information

Non-clinical testing has demonstrated that the ProVee Expander is MR Conditional with the following considerations.

Name/identification of device	ProVee® Expander
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	30 T/m (3000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Any transmit coil may be used
RF receive coil type	Any receive coil may be used
Maximum whole body SAR (W/kg)	2.0 W/kg
Limits on scan duration	60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 10 minutes if this limit is reached
MR image artifact	The presence of this implant produced an image artifact of approximately 8 mm when imaged with a gradient echo pulse sequence and a 3 T MRI system

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Device Specification Precautions

- Care must be taken when catheterising a patient who has an implanted ProVee Expander. It is recommended that a straight catheter of the smallest catheter size that will treat the condition is utilised. Use of a coudé tip catheter may result in implant movement.
- Care must be taken when performing cystoscopic procedures in a patient who has an implanted ProVee Expander, particularly in the first 3 months.
- In the event of any surgical resection of the prostate the surgeon should assess whether or not the ProVee Expander should be left in situ.

Removing a ProVee Expander

Grasper removal method:

1. Under direct vision insert a ≥19.4Fr non-beaked sheath with a minimum working channel of 12Fr into the prostatic urethra until the implant is visualised.
2. Insert a 10-10.5Fr rigid inverted rat tooth grasper down the working channel of the sheath.
3. Grasp a distal apex of the implant and track the working channel of the sheath over the grasped apex by moving the sheath forwards.
4. Keeping the grasper closed, firmly pull the implant through the working channel of the sheath by retracting the grasper into the sheath.
5. Inspect the implant to confirm that the entire implant has been removed.

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